

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

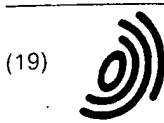
Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



Europäisches Patentamt
European Patent Office
Office européen des brevets



(11) **EP 1 214 103 B1**

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention
of the grant of the patent:
22.10.2003 Bulletin 2003/43

(51) Int Cl.⁷: **A61L 2/20, A61L 2/24**

(86) International application number:
PCT/GB00/03606

(21) Application number: **00960861.3**

(87) International publication number:
WO 01/021223 (29.03.2001 Gazette 2001/13)

(22) Date of filing: **20.09.2000**

(54) METHODS AND APPARATUS FOR VAPOUR PHASE STERILISATION

METHODE UND APPARAT ZUR DAMPFPHASENSTERILISATION

PROCEDE ET APPAREIL DE STERILISATION EN PHASE VAPEUR

(84) Designated Contracting States:
**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU
MC NL PT SE**

• **WATLING, David**
Westcott, Surrey RH4 3LB (GB)

(30) Priority: **21.09.1999 GB 9922364**

(74) Representative: **Bayliss, Geoffrey Cyril et al**
BOULT WADE TENNANT,
Verulam Gardens
70 Gray's Inn Road
London WC1X 8BT (GB)

(43) Date of publication of application:
19.06.2002 Bulletin 2002/25

(73) Proprietor: **Bioquell UK Limited**
Andover, Hampshire SP10 5AA (GB)

(56) References cited:
EP-A- 0 774 263 WO-A-00/38745
US-A- 5 173 258 US-A- 5 906 794

(72) Inventors:
• **MARTIN, Anthony Michael**
Charlton, Andover SP10 4AS (GB)

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

EP 1 214 103 B1

Description

[0001] The present invention relates to a method and an apparatus for sterilising the interior of a chamber using either a two component or a multicomponent vapour, one component of which will be water.

[0002] There are numerous applications for sterilising the interior of a chamber including its contents in the pharmaceutical, biotechnology, and food industries, as well as the medical world. A number of compounds have been used as sterilising agents some of which are only partially effective and some of which have serious side effects because they are toxic, corrosive, or can cause other environmental damage. Formaldehyde has long been used as a cheap and quite effective sterilising agent but doubts over its safety and environmental persistence may prevent continued use. Hydrogen peroxide is a simple and cheap compound with good sterilising properties. Its major advantage is that it can be decomposed to water and oxygen, which are totally harmless products. In the vapour phase, hydrogen peroxide can be used to treat work areas of size from safety cabinets to clean rooms. In all gas phase sterilisation, deep layers of contamination will not be effected and good cleaning procedures are necessary as a preliminary to gas phase sterilisation.

[0003] Hydrogen peroxide gas sterilisation and decontamination systems have been designed in order to avoid condensation, and as such both flow through and recirculating systems have been so organised as to keep the vapour concentrations, especially of water, below the dew point. Examples of such systems are described in EP-A-0486623B1, GB-B-2217619, WO-A-89/06140 and GB-A-2308066.

[0004] More recent work has shown that for rapid surface sterilisation and decontamination in rooms and smaller chambers, or isolators, condensation of a mixture of vapours of a gaseous decontaminant such as hydrogen peroxide and water is essential. It is now believed that gaseous surface sterilisation using hydrogen peroxide is a condensation process so it would seem sensible to examine the process, to see how it may be optimised to take advantage of the condensation process. This knowledge may then be applied not only the sterilisation process using hydrogen peroxide gas but also other mixtures of sterilising gases that rely on condensation for their activity.

[0005] In the apparatus described in EP-A-0 486 623 B1 the air/gas mixture is circulated through the sealed chamber to be sterilised and then through the apparatus to produce and control the gas mixture. The gas returning to the apparatus is cleansed of any hydrogen peroxide gas and also dried before more water vapour and hydrogen peroxide gas are added. This cleansing and drying process is likely to be wasteful, as the vapours removed from the circulating gas must be replaced so that condensation may occur in the sealed chamber. The only reason for the removal of these vapours would

be if the concentration of the hydrogen peroxide gas had been reduced because of decomposition.

[0006] It is now well understood that vapour phase decomposition does not occur at room temperatures, such homogenous decomposition only happens at elevated temperatures as reported in the paper "HYDROGEN PEROXIDE" by WALTER C. SCHUMB CHARLES N. SATTERFIELD, and RALPH L. WENTWORTH, published in AMERICAN CHEMICAL SOCIETY, MONOGRAPH SERIES, Catalog Card Number 55-7807, Chapter 8. Decomposition does however happen on surfaces, which are catalytic, but this appears to be very small amounts. To date no observer has seen a measurable increase in oxygen concentration, and the measured hydrogen peroxide gas concentrations conform very closely to the saturated vapour pressures of the original aqueous solution that is evaporated into the air stream. All of the indications are therefore that the amount of vapour phase decomposition of hydrogen peroxide is very small.

[0007] Since this sterilisation process relies on condensation of the hydrogen peroxide vapour then the most critical parameter is the rate at which this condensation may be achieved. The amount of hydrogen peroxide vapour available for condensation within the sealed enclosure will depend on the vapour concentration delivered to the chamber and the concentration leaving the chamber. The difference between these two amounts will be the quantity of hydrogen peroxide that is available to form a film of condensation.

[0008] The maximum concentration of vapour that can be delivered to the chamber depends on the temperature of the gas stream entering the chamber, the concentration of the aqueous sterilising solution being evaporated into the gas stream and the total water content of the gas. The carrier gas, normally air, that is used to transport the sterilising vapours through the total system will never be perfectly dry, even after passing through the drying system. This additional water in the carrier gas will dilute the hydrogen peroxide to a small extent and this additional water will reduce the amount of hydrogen peroxide that may be carried by the gas. The concentration of the vapour leaving the sealed chamber, once stable conditions have been reached, will be determined by the saturated vapour pressure for the conditions at the exit of the sealed chamber. Thus, if it is assumed that only insignificant amounts of decomposition occur, then the rate of condensation will depend on the concentration of the gases delivered to the chamber and the temperature of the gases leaving the chamber.

[0009] In general there are two factors that are important when considering a gaseous surface sterilisation process. The first and most important is to be sure that the process has been successful and the second is to achieve sterilisation in the minimum possible time. The most common technique for assuring sterility is to develop a cycle and to test the performance with biological

indicators. This cycle development will include optimisation of each phase of the sterilisation cycle. This is a complex issue as there are many parameters to be considered during the optimisation process apart from the obvious considerations of gas concentration and flow. Some of the less obvious ones are the starting value of the relative humidity, the moisture content of any micro-organism, the rate of condensation, and the length of time it may take for the condensate to kill any microorganism. The technique used for the removal of the sterilant gas at the end of the cycle will also have marked influence on the total cycle time.

[0010] The optimised cycle then becomes fixed using the same physical parameters such as flow rates, times etc., but does not take into account any external factors that may change, e.g. the external temperature which will have an influence on the effectiveness of the cycle.

[0011] The problem with this fixed technique is that if some external influences change which have not been taken into consideration during the cycle development then a cycle, although properly developed, may become unsuccessful. The best method to overcome this difficulty is to measure those parameters that actually cause the sterilisation and use these measurements to control the cycle, rather than to use a set of predetermined factors to run identical cycles. The technique of using the measurements to control the cycle will lead to changes in the details of the cycle to counteract any changes in the circumstances surrounding the process.

[0012] This procedure also has the advantage of ensuring the minimum reliable cycle time, since the process will progress to a point where it is effective and no further. It is not necessary to add large safety margins to the cycle to ensure that it is effective, as the point at which it is effective is known from the measurements.

[0013] The objects of the present invention are to control the sterilisation cycle using sensors, and to provide a recirculating system that does not require the steps of removing water vapour and sterilising gas mixtures during the critical sterilisation phase of the cycle.

[0014] US-A-5906794 discloses a flow-through vapour phase sterilisation system which includes a sealable chamber with an inlet port and outlet port and a circuit fluidly connected to the chamber ports to provide a closed loop flow path for recirculating a carrier gas into through and out of the chamber. The system also includes a liquid sterilant vaporiser unit for delivering a vaporised liquid sterilant into the carrier gas flow upstream of the inlet port and a converter for converting the sterilant vapour to a form suitable for disposal is fluidly connected to the conduit circuit downstream of the chamber outlet port. A drying unit is included in the circuit downstream of the converter and has a valve for controlling flow to a first flow path through an air dryer and thence to the vaporiser or a second flow path which by passes the air dryer. By varying the amount of fluid through the first and second flow paths a selected portion of the carrier gas can be routed to by pass the dryer

and the humidity of the carrier gas can be regulated to maintain a predetermined percent saturation sterilant vapour in the chamber as the sterilising cycle proceeds.

[0015] WO-A-00/38745 is a document relevant in accordance with EPC Article 54(3) and (4) and discloses a batch process for sterilising an article using concentrated hydrogen peroxide vapour. The article is placed into a steriliser and hydrogen peroxide and water are delivered to the steriliser. The hydrogen peroxide and water are vaporised to form a vapour comprising hydrogen peroxide and water. The concentration of hydrogen peroxide in the vapour and water in the vapour are monitored and water vapour is withdrawn from the steriliser to increase and therefore concentrate the hydrogen peroxide until the ratio of hydrogen peroxide to water is at a desired level to achieve sterilisation.

[0016] It is an object of the present invention to provide a continuous sterilising system in which concentration of sterilant vapour in the chamber to be sterilised is built up more rapidly than hitherto possible to achieve quick condensation of sterilant in the chamber to shorten the overall sterilisation cycle.

[0017] This invention provides a method of sterilising a sealable enclosure comprising the steps of circulating a carrier gas and sterilant through the enclosure and through a flow path having an outlet from the enclosure and an inlet to the enclosure, any sterilant in the gas flow received from the enclosure being rendered suitable for disposal, and the content of water vapour being reduced following which the gas flow is heated and further sterilant is added to sterilise the enclosure, wherein the flow path has two parallel branches in one of which any sterilant in the gas flow is rendered suitable for disposal and any water vapour content in the gas is reduced and in the other of which the carrier gas is heated and sterilant is added to the gas. the method further comprising the steps of initially circulating said carrier gas through said one branch, monitoring the moisture content of the gas in the enclosure and terminating flow of carrier gas through said one branch when the relative humidity in the enclosure has been reduced to a predetermined level such that the surfaces of the enclosure are relatively dry, initiating flow of the carrier gas through said other branch and adding a sterilant vapour or vapours to the gas passing through the other branch until condensation of the sterilant takes place in the enclosure, terminating supply of sterilant to the carrier gas, continuing to circulate the carrier gas substantially saturated with sterilant vapour for a predetermined time to ensure sterilisation of the enclosure terminating flow through said other branch and redirecting the flow of carrier gas through said one branch to extract the sterilant from the gas enclosure to render the sterilant suitable for disposal and to reduce the relative humidity of the carrier gas.

[0018] More specifically the invention provides a method of sterilising a sealable enclosure comprising the steps of initially reducing the relative humidity in the

enclosure to about 30 to 40%, circulating a carrier gas to the enclosure, raising the temperature of the circulating gas above ambient, supplying a sterilant vapour or vapours to the circulating carrier gas sufficient to saturate substantially the gas whereby on cooling in the enclosure, a condensate of the sterilant vapour is formed on surfaces in the enclosure, distributing the gas/vapour throughout the enclosure to ensure that the condensate is formed on all surfaces in the enclosure, measuring the amount of condensate formed on a surface of the enclosure and continuing to circulate the gas/vapour until a required amount of condensate has formed in the enclosure terminating supply of sterilant vapour to the gas whilst continuing to circulate the saturated gas/vapour to maintain the condensate on the surface for a predetermined period of time and finally extracting the sterilant vapour from the carrier gas whilst continuing to circulate the carrier gas through the enclosure to extract the condensate from the enclosure.

[0019] Preferably the sterilant vapour is extracted from the carrier gas by breaking down the vapour into disposable constituents.

[0020] It is also preferred that the sterilant vapour is hydrogen peroxide and water vapour. In this case the hydrogen peroxide extracted from the chamber with the circulating gas is subjected to catalytic action to break the hydrogen peroxide down into water vapour and oxygen, the former being extracted from the gas before the gas is recirculated through the enclosure.

[0021] The initial step of reducing the relative humidity in the enclosure may be carried out by circulating the carrier gas through the chamber and extracting water vapour from the circulating gas outside the chamber.

[0022] The relative humidity in the enclosure may be reduced initially to about 35%. In addition, the enclosure may be held at said reduced relative humidity for a period of time according to the size of enclosure and flow rate of gas to ensure dryness of said surfaces in the enclosure.

[0023] Entry to one branch is closed and entry to the other branch may be opened and vice versa to provide flow through one or other of the branches. For example, valve means may permit flow into one branch and not the other and vice versa.

[0024] Alternatively, pump means may be provided in said parallel branches and are used to cause gas flow along one or other of the parallel branches in the flow path.

[0025] The invention further provides apparatus for sterilising a sealable enclosure comprising a circuit for flow of a gas or gasses, the circuit having means to receive and connect an enclosure to be sterilised in the circuit to form a closed circuit therewith, means to circulate gas through the circuit and enclosure, and having two parallel branches in the circuit one of which contains means to deactivate a sterilant to be added to the carrier gas flowing through the circuit and means to dehumidify the gas and the other of which branches contains means

to heat the gas and means to supply a sterilant vapour or vapours to the gas, the apparatus further comprising control means for determining through which of the parallel branches the gas flows, the control means including means to determine the relative humidity of the gas exiting the enclosure and being operable to maintain flow through said one branch passage open until the relative humidity falls below a predetermined level and then to terminate flow through that branch and to initiate flow in the other branch and means to measure condensation in the enclosure to terminate flow in said other branch and to initiate flow in said one branch when the required amount of condensation has built up in the enclosure.

[0026] The apparatus may further include means to distribute the gas/vapours throughout the enclosure to ensure that the condensate is formed on all surfaces in the enclosure.

[0027] It has been found that in aqueous solutions of hydrogen peroxide very fast kill rates are achieved even at 10% hydrogen peroxide concentrations with even faster kills at 20% solution. Since we believe that gaseous surface sterilisation is a micro condensation process, then it may be considered to be analogous to the work

"THE STERILISING EFFECT AGAINST BACILLUS SUBTILIS SPORES OF HYDROGEN PEROXIDE AT DIFFERENT TEMPERATURES AND CONCENTRATIONS," by P. SWARTLING and B. LINDGREN J. DAIRY RES. (1968), 35,423. This gives a good guide as to the expected results that may be achieved with a gaseous condensation process.

[0028] This also suggests that should some small amount of decomposition occur because of surface catalysis of the gas then kills would still be achieved. In reality such decomposition appears to be very small indeed as indicated by the gas concentration data.

[0029] The following is a description of some specific embodiments of the invention, reference being made to the accompanying drawings in which:

Figure 1 is a diagrammatic view of a sealed chamber and a sterilisation circuit connected to the chamber for sterilising the interior and contents of the chamber using a gas carrying an aqueous vapour of a liquid sterilant, the circuit having two pumps or fans.

Figure 2 is a diagrammatic view of a sealed chamber and a further form of circuit connected to the chamber for sterilisation of the interior of the chamber and its contents using a gas containing an aqueous vapour of a liquid sterilant, the circuit having a single pump or fan.

[0030] The apparatus comprises a sealed chamber 10, and incorporates a dual circuit for dehumidification, sterilising and aeration of the sealed chamber 10. A carrier gas, i.e. air, and a sterilising gas or gases are drawn from the sealed chamber to the apparatus through

sealed connections fluidly connecting the chamber to the apparatus.

[0031] The apparatus comprises a gas flow circuit 12 containing in series, a gas monitor 13 a temperature and humidity monitor 14 and a flow measurement device 15. The gas monitor is an electrochemical cell giving a signal proportional to the gas concentration or can be a near infra-red spectrophotometer. Suitable temperature and humidity sensors 14 are commonly available as a single commercial instrument, and any such device that is resistant to hydrogen peroxide vapour would be suitable for this application. The most suitable, and cost effective, flow measurement 15 system is based on the measurement of the pressure difference across a restriction in the flow, typically an orifice plate.

[0032] Attached to the sealed chamber is a condensation measurement system 16. Proprietary systems are not readily available, but techniques have been developed that rely on the change in reflectivity of a surface in the chamber to indicate the mass of condensate that has formed. Alternative techniques that may include measuring equipment be mounted on the outside of the chamber.

[0033] Downstream of the flow measurement system the circuit divides into two parallel branches 17, 18. Each branch has a fan 18, 19 and each fan has an associated non-return valve 21. As the pressure required to force the circulating gas round the system is generally not large then a standard variable speed centrifugal fan would suffice for such an application. The non-return valves are required to ensure that there is no back flow in the wrong direction. Simple flap devices are all that is required in this application. In the first parallel branch 17 is a system 22 to deactivate and remove the sterilant gas or gases from the carrier gas, and a further system 23 to dehumidify the gas stream. Downstream of the dehumidification system is a heater 24 to raise the circulating gas temperature. The deactivating system for the sterilant gas comprises a catalyst bed, which decomposes the vapour to harmless components. For hydrogen peroxide gas a suitable catalyst would be ruthenium on inert pellets which decomposes the gas to water vapour and oxygen.

[0034] A desiccant dryer may perform the dehumidification process, but a more suitable technique would be to reduce the gas temperature using a refrigeration system. The reduction in temperature causes the water vapour to condense with the products of decomposition. The resulting condensate and decomposition products may then be pumped away. It is necessary to raise the circulating gas temperature after dehumidification and an electric heater 24 or other heating means is placed downstream of the dehumidifier for the purpose.

[0035] In the second parallel branch is a heater 25 to raise the gas temperature prior to entering an evaporator 26, in which the liquid sterilant is turned to vapour by heating. A liquid sterilant supply 27 controls the liquid flow to the evaporator.

[0036] The heater 25 may be of a similar construction to the other heater 24. The evaporator is a flash evaporator in which the liquid sterilant is evaporated by dropping under gravity a stream of liquid onto a heated surface. The flow of liquid from the sterilant supply is fed onto the heated surface at a selected rate by using a variable speed pump, which is controlled from a flow measuring system. The gas temperature entering the sealed chamber 10 is measured at 28 using a standard temperature probe. Gas entry to the chamber 10 is through a gas distribution system including a rotating nozzle arrangement which projects gas at high temperature and velocity to every part of the chamber. In addition a system for control gas pressure in the circuit to raise or reduce pressure as required is provided.

[0037] The components in the alternative arrangement shown in Figure 2 are the same, with the same numbering except for the fan and valve arrangement. In Figure 2 the gas or gases are driven round the system by a single fan of pump 30. The gas or gas mixtures leaving the fan or pump pass to a three way valve 31, which diverts the flow either to the first parallel branch by connecting port A to port C, or to the second parallel branch by connecting port A to port B. The valve is typically an electrically driven three-way ball valve.

[0038] The method of sterilising the enclosure using the above apparatus comprises the steps of reducing the relative humidity in the enclosure, then circulating a carrier gas containing an aqueous vapour of the sterilising gas or gases, and finally removing the sterilising gas or gases.

[0039] The first phase of reducing the relative humidity is essential to ensure that all of the surfaces inside the sealable chamber are at the same state of dryness.

During the second phase the sterilising gas or gases are delivered to the sealed chamber at an elevated temperature in order that as much as possible of the sterilant may be transported into the sealed chamber. The third and final stage is the removal of the sterilant gas or gases by passing clean dry carrier gas into the sealed chamber to carry away the active gas or gases.

[0040] The first phase of reducing the humidity may be in two parts, the first to reduce the relative humidity to a pre-selected value, and a second part to hold the humidity at that value to allow the sealed chamber to come to a stable state.

[0041] Similarly the second phase when the gas or gases are passed into the sealed chamber is in two parts. The first part is to raise the concentration and generate the required level of condensation on the surfaces, with a second dwell part to allow the condensate to act on the microorganisms. The level of condensation is measured during the first part of the second phase and when it has reached the required level the supply of sterilising gas or gases is stopped but the carrier gas with the associated saturated vapours continues to circulate. The circulating saturated vapour prevents evaporation of the layer of condensation allowing the liquid film to

act on the microorganisms.

[0042] During the third and final phase of the sterilisation cycle the carrier gas together with the sterilising gas or gases is circulated through a system to render the active gases harmless, so that it may be taken away, whilst at the same time removing the water vapour in a dehumidifier. The clean carrier gas is then returned to the sealed chamber where it gathers more of the active gas or gases thus further reducing to the level of the active ingredients. This process continues until the amount of active ingredients have been reduced to an acceptable level.

1. The relative humidity (RH) must be controlled at the start of the sterilisation cycle. We have established that the optimum value is between 30 and 40%. There are two points to be considered about the starting value of RH, the first is to obtain the shortest possible cycle (this requires the RH to be reduced to about 35%), and the second is to achieve a repeatable cycle. The repeatability depends on using the same starting value of RH and this may well have to be higher than 35% depending on local conditions. As it may not always be practical to achieve a starting value of 35% for the RH then it is essential that the same starting value is always used. Higher values of RH will increase the time required to achieve sterilisation as the condensate forming on surfaces will be diluted by any water that is present.

2. The amount of condensation is important; if too much is formed, the time to remove the surface layer after sterilisation has been achieved will be increased, as it would take longer to dry the surfaces. If insufficient condensation is allowed to form then sterilisation will not take place. The accurate measurement of this surface layer is essential to the process.

3. From the work of Swartling et al referred to above, it is clear that some "soaking" time will be required for the condensed liquid to be effective. This is built into the sterilisation cycle as a dwell period, a safety margin should be allowed within this dwell period to ensure that a total kill has been achieved. This period will normally be no more than a few minutes including the safety margin.

4. The distribution of the hot gas entering the chamber is also important. As the gas enters the chamber it will rapidly start to cool and form condensation. If the gas is not thoroughly mixed as it enters the chamber then there will be sites of preferential condensation. If this should happen then it follows that other areas within the chamber will have less condensation, and to achieve a total kill in all areas an excess of gas will be required. This excess will be unevenly distributed and also take longer to remove at the end of the cycle when it is required to return the chamber to normal use.

5. The measurement of the concentration and temperature of the gas leaving the chamber tells the system that saturated vapour pressure has been reached. Whilst this is not a critical parameter it does indicate that condensation will form. If the concentration is too low and condensation does not form then the cycle should be aborted and these measurements will confirm that action.

[0043] Thus the process cycle comprises the following steps:

1. The chamber is brought to a starting value of RH, normally 35%. The chamber should be held at this level for a few minutes to ensure all of the surfaces have been brought to equilibrium.

2 Sterilising gas or gases and water vapour are passed into the chamber at an elevated temperature and distributed so as to generate an even layer of condensation. The amount of condensation is measured and when it has reached a sufficient value the gas and water vapour generator is switched off.

3. The condensed gas or gases and water remain on the surfaces for a sufficient length of time to cause sterilisation.

4. At the end of the dwell period the chamber is fed with clean dry air, which causes the surface condensation to evaporate and is therefore cleared from the chamber.

Claims

1. A method of sterilising a sealable enclosure comprising the steps of circulating a carrier gas and sterilant through the enclosure and through a flow path having an outlet from the enclosure and an inlet to the enclosure, any sterilant in the gas flow received from the enclosure being rendered suitable for disposal, and the content of water vapour being reduced following which the gas flow is heated and further sterilant is added to sterilise the enclosure, **characterised in that** the flow path has two parallel branches in one of which any sterilant in the gas flow is rendered suitable for disposal and any water vapour content in the gas is reduced and in the other of which the carrier gas is heated and sterilant is added to the gas, the method further comprising the steps of initially circulating said carrier gas through said one branch, monitoring the moisture content of the gas in the enclosure and terminating flow of carrier gas through said one branch when the relative humidity in the enclosure has been reduced to a predetermined level such that the surfaces of the enclosure are relatively dry, initiating flow of the carrier gas through said other branch and adding a sterilant vapour or vapours to the gas passing

- through the other branch until condensation of the sterilant takes place in the enclosure, terminating supply of sterilant to the carrier gas, continuing to circulate the carrier gas substantially saturated with sterilant vapour for a predetermined time to ensure sterilisation of the enclosure terminating flow through said other branch and redirecting the flow of carrier gas through said one branch to extract the sterilant from the gas enclosure to render the sterilant suitable for disposal and to reduce the relative humidity of the carrier gas.
2. A method as claimed in claim 1, wherein entry to one branch is closed and entry to the other branch is opened and vice versa to provide flow through one or other of the branches.
 3. A method as claimed in claim 2, wherein valve means permit flow into one branch and not the other and visa versa.
 4. A method as claimed in claim 2, wherein pump means are used in the flow path to circulate said carrier gas.
 5. A method as claimed in claim 2, wherein pump means are provided in said parallel branches and are used to cause gas flow along one or other of the parallel branches in the flow path.
 6. A method as claimed in any of claim 1 to 5, wherein water vapour is removed from the gas in said one branch by cooling the gas to cause the water vapour to condense, the resulting condensate being removed.
 7. A method as claimed in claim 6, wherein the gas cooled in said one branch is heated following said cooling step.
 8. A method as claimed in any of the preceding claims comprising the steps of initially reducing the relative humidity in the enclosure to about 30 to 40%, circulating a carrier gas to the enclosure, raising the temperature of the circulating gas above ambient, supplying a sterilant vapour or vapours to the circulating carrier gas sufficient to saturate substantially the gas whereby on cooling in the enclosure, a condensate of the sterilant vapour is formed on surface in the enclosure, distributing the gas/vapour throughout the enclosure to ensure that the condensate is formed on all surfaces in the enclosure, measuring the amount of condensate formed on a surface of the enclosure and continuing to circulate the gas/vapour until a required amount of condensate has formed in the enclosure terminating supply of sterilant vapour to the gas whilst continuing to circulate the saturated gas/vapour to maintain the condensate on the surface for a predetermined period of time and finally extracting the sterilant vapour from the carrier gas whilst continuing to circulate the carrier gas through the enclosure to extract the condensate from the enclosure.
 9. A method as claimed in claim 8, wherein the sterilant vapour is extracted from the carrier gas by breaking down the vapour into disposable constituents.
 10. A method as claimed in claim 8 or 9, wherein the sterilant vapour is hydrogen peroxide and water vapour.
 11. A method as claimed in claim 10, wherein the hydrogen peroxide extracted from the chamber with the circulating gas is subjected to catalytic action to break the hydrogen peroxide down into water vapour and oxygen, the former being extracted from the gas before the gas is recirculated through the enclosure.
 12. A method as claimed in any of claims 8 to 11, wherein the initial step of reducing the relative humidity in the enclosure is carried out by circulating the carrier gas through the chamber and extracting water vapour from the circulating gas outside the chamber.
 13. A method as claimed in any of claims 8 to 12, wherein the relative humidity in the enclosure is reduced to about 35%.
 14. A method as claimed in any of claims 8 to 13, wherein the enclosure is held at said reduced relative humidity for a period of time according to the size of the enclosure and flow rate of gas to ensure dryness of said surfaces in the enclosure.
 15. A method as claimed in any of claims 8 to 14, wherein the condensate is maintained on the surfaces within the enclosure for a predetermined period to ensure sterilisation of the surfaces.
 16. An apparatus for sterilising a sealable enclosure (10) comprising a circuit (12) for flow of a gas or gasses, the circuit having means to receive and connect an enclosure to be sterilised in the circuit to form a closed circuit therewith, means (19,20) to circulate gas through the circuit and enclosure, and having two parallel branches (17, 18) in the circuit one of which contains means (22) to deactivate a sterilant to be added to the carrier gas flowing through the circuit and means (23) to dehumidify the gas and the other of which branches contains means (25) to heat the gas and means (26) to supply a sterilant vapour or vapours to the gas, the apparatus further comprising control means (13 to 16)

for determining through which of the parallel branches the gas flows, the control means including means (14) to determine the relative humidity of the gas exiting the enclosure and being operable to maintain flow through said one branch (17) passage open until the relative humidity falls below a predetermined level and then to terminate flow through that branch and to initiate flow in the other branch (18) and means (16) to measure condensation in the enclosure to terminate flow in said other branch and to initiate flow in said one branch when the required amount of condensation has built up in the enclosure.

17. An apparatus as claimed in claim 16, **characterised in that** a fan (20) provided in the circuit (12) between the enclosure (10) and the parallel branches (17, 18) of the circuit to cause gas flow around the circuit and valve means (31) are provided at the entry to the first and second branches which are selectively operable to permit flow through one or the other of the branches.
18. An apparatus as claimed in claim 16, **characterised in that** fans (19, 20) are provided in both branches in the circuit which are selectively operable to cause flow of gas through one or other of the branches (17, 18).
19. An apparatus as claimed in any of claims 16 to 18, **characterised in that** means are provided to distribute the gas/vapours throughout the enclosure (10) to ensure that condensate is formed on all surfaces in the enclosure.
20. An apparatus as claimed in any of claims 16 to 19, the means to deactivate the sterilant in said one branch comprise means (22) to break the sterilant extracted from the enclosure (10) down into disposable constituents.
21. An apparatus as claimed in claim 20, the sterilant is hydrogen peroxide vapour and water vapour and the means (22) to break the sterilant down comprise catalytic means to act on the hydrogen peroxide to break the hydrogen peroxide down into water vapour and oxygen.
22. An apparatus as claimed in any of claims 16 to 21, the means (23) to lower the relative humidity of the circulating carrier gas comprise refrigeration means to cool the gas to extract moisture therefrom by condensation and means (24) to heat the gas above ambient following said condensation process.

Patentansprüche

1. Verfahren zum Sterilisieren eines versiegelbaren Behälters, das die Schritte des Umwälzens eines Trägergases und eines Sterilisierungsmittels durch den Behälter und durch einen Durchflussweg mit einem Auslass aus dem Behälter und einem Einlass in den Behälter aufweist, wobei jedes Sterilisierungsmittel in dem Gasstrom, der aus dem Behälter erhalten wird, für eine Entsorgung geeignet gemacht ist, und der Gehalt an Wasserdampf reduziert, anschließend der Gasstrom erwärmt und weiteres Sterilisierungsmittel hinzugegeben wird, um den Behälter zu sterilisieren, **dadurch gekennzeichnet, dass** der Durchflussweg zwei parallele Äste aufweist, wobei in einem davon jedes Sterilisierungsmittel in dem Gasstrom für eine Entsorgung geeignet gemacht ist und jeder Wasserdampfgehalt in dem Gas vermindert wird, und wobei in dem anderen davon das Trägergas erwärmt und ein Sterilisierungsmittel zu dem Gas hinzugegeben wird, wobei das Verfahren ferner die folgenden Schritte aufweist:
 - Anfängliches Umwälzen des Trägergases durch den einen Ast,
 - Überwachen des Feuchtigkeitsgehalts des Gases in dem Behälter, und
 - Beenden des Trägergasflusses durch den einen Ast, wenn die relative Feuchtigkeit in dem Behälter auf ein vorbestimmtes Niveau vermindert worden ist, so dass die Oberflächen des Gehäuses relativ trocken sind,
 - Initiieren eines Flusses des Trägergases durch den anderen Ast und Hinzugeben von Sterilisierungsmitteldampf oder -dämpfen zu dem Gas, das durch den anderen Ast hindurchgeht, bis eine Kondensation des Sterilisierungsmittels in dem Behälter stattfindet,
 - Beenden der Zufuhr von Sterilisierungsmittel zu dem Trägergas,
 - Fortsetzen des Umwälzens des Trägergases, das im Wesentlichen mit dem Sterilisierungsmitteldampf gesättigt ist, für eine vorbestimmte Zeit, um eine Sterilisation des Behälters sicherzustellen,
 - Beenden des Flusses durch den anderen Ast, und
 - Umleiten des Trägergasflusses durch den einen Ast, um das Sterilisierungsmittel aus dem Gasbehälter zu extrahieren, um das Sterilisierungsmittel geeignet für eine Entsorgung zu machen und um die relative Feuchtigkeit des Trägergases zu vermindern.
2. Verfahren nach Anspruch 1, **dadurch gekennzeichnet, dass** der Eingang zu einem Ast geschlossen und der Ein-

- gang zu dem anderen Ast geöffnet ist und umgekehrt, um einen Fluss durch den einen oder anderen der Äste zur Verfügung zu stellen.
3. Verfahren nach Anspruch 2, 5
dadurch gekennzeichnet, dass eine Ventileinrichtung einen Fluss in einen Ast und nicht den anderen ermöglicht und umgekehrt.
 4. Verfahren nach Anspruch 2, 10
dadurch gekennzeichnet, dass Pumpeinrichtungen in dem Durchflussweg verwendet werden, um das Trägergas umzuwälzen.
 5. Verfahren nach Anspruch 2, 15
dadurch gekennzeichnet, dass Pumpeinrichtungen in den parallelen Ästen zur Verfügung gestellt und verwendet werden, um einen Gasfluss entlang des einen oder des anderen der parallelen Äste in dem Durchflussweg zu bewirken. 20
 6. Verfahren nach einem der Ansprüche 1 - 5, 25
dadurch gekennzeichnet, dass Wasserdampf aus dem Gas in dem einen Ast entfernt wird, indem das Gas gekühlt wird, um zu bewirken, dass der Wasserdampf kondensiert, wobei das resultierende Kondensat entfernt wird.
 7. Verfahren nach Anspruch 6, 30
dadurch gekennzeichnet, dass das in dem einen Ast gekühlte Gas anschließend an den Kühlungsschritt erwärmt wird.
 8. Verfahren nach einem der vorhergehenden Ansprüche, 35
das die folgenden Schritte aufweist:
 - Anfängliches Vermindern der relativen Feuchtigkeit in dem Behälter auf etwa 30% - 40%, 40
 - Umwälzen eines Trägergases zu dem Behälter,
 - Erhöhen der Temperatur des umgewälzten Gases über Umgebungstemperatur,
 - Zuführen von Sterilisierungsmitteldampf oder -dämpfen zu dem umgewälzten Gas in einer Menge, die ausreicht, um das Gas im Wesentlichen zu sättigen, wobei beim Abkühlen in dem Behälter ein Kondensat von dem Sterilisierungsmitteldampf an den Oberflächen des Behälters gebildet wird, 45
 - Verteilung des Gases/Dampfes überall in dem Behälter, um sicherzustellen, dass das Kondensat an allen Oberflächen in dem Behälter gebildet wird, 50
 - Messen der Menge an Kondensat, das an einer Oberfläche des Behälters gebildet ist, und 55
 - Fortsetzen des Umwälzens des Gases/Dampfes, bis eine erforderliche Menge des Kondensats in dem Behälter gebildet worden ist.
 - Beenden der Versorgung von Sterilisierungsmitteldampf zu dem Behälter während eines Fortsetzens des Umwälzens des gesättigten Gases/Dampfes, um das Kondensat an den Oberflächen für eine vorbestimmte Zeitdauer zu erhalten, und schließlich
 - Extrahieren des Sterilisierungsmitteldampfes aus dem Trägergas, während eines Fortsetzens des Umwälzens des Trägergases durch den Behälter, um das Kondensat aus dem Behälter zu extrahieren.
 9. Verfahren nach Anspruch 8, 10
dadurch gekennzeichnet, dass der Sterilisierungsmitteldampf aus dem Trägergas extrahiert wird, indem der Dampf in entsorgbare Bestandteile zerlegt wird.
 10. Verfahren nach Anspruch 8 oder 9, 15
dadurch gekennzeichnet, dass der Sterilisierungsmitteldampf Wasserstoffperoxid und Wasserdampf ist.
 11. Verfahren nach Anspruch 10, 20
dadurch gekennzeichnet, dass das Wasserstoffperoxid, das aus der Kammer mit dem umgewälzten Gas extrahiert wird, einer katalytischen Wirkung unterworfen wird, um das Wasserstoffperoxid in Wasserdampf und Sauerstoff zu zerlegen, wobei Ersteres aus dem Gas extrahiert wird, bevor das Gas wieder durch den Behälter umgewälzt wird.
 12. Verfahren nach einem der Ansprüche 8 - 11, 25
dadurch gekennzeichnet, dass der anfängliche Schritt des Reduzierens der relativen Feuchtigkeit in dem Behälter durchgeführt wird, indem das Trägergas durch die Kammer umgewälzt und Wasserdampf aus dem umgewälzten Gas außerhalb der Kammer extrahiert wird.
 13. Verfahren nach einem der Ansprüche 8 - 12, 30
dadurch gekennzeichnet, dass die relative Feuchtigkeit in dem Behälter auf etwa 35% vermindert wird.
 14. Verfahren nach einem der Ansprüche 8 - 13, 35
dadurch gekennzeichnet, dass der Behälter bei der verminderten relativen Feuchtigkeit für eine Zeitdauer entsprechend der Größe des Behälters und der Flussrate des Gases gehalten wird, um eine Trockenheit der Oberflächen in dem Behälter sicherzustellen.
 15. Verfahren nach einem der Ansprüche 8 - 14, 40
dadurch gekennzeichnet, dass das Kondensat an den Oberflächen innerhalb des Behälters für eine vorbestimmte Zeitdauer auf-

rechterhalten wird, um eine Sterilisation von den Oberflächen sicherzustellen.

16. Vorrichtung zum Sterilisieren eines versiegelbaren Behälters (10),
der Folgendes aufweist:

- Eine Leitung (12) für einen Fluss eines Gases oder von Gasen, wobei die Leitung Mittel zum Erhalten und Verbinden eines in der Leitung zu sterilisierenden Behälters aufweist, um damit eine geschlossene Leitung zu bilden,
- Mittel (19, 20), um Gas durch die Leitung und den Behälter umzuwälzen, und wobei die Leitung zwei parallele Äste (17, 18) aufweist, wobei einer von ihnen Mittel (22) aufweist, um ein Sterilisierungsmittel zu deaktivieren, das zu dem Trägergas hinzugegeben wird, das durch die Leitung strömt, und Mittel (23) aufweist, um das Gas zu entfeuchten, und wobei der andere der Äste Mittel (25) zum Erwärmen des Gases und Mittel (26) aufweist, um einen Sterilisierungsmitteldampf oder -dämpfe zu dem Gas zuzuführen, wobei die Vorrichtung ferner Regelmittel (13 - 16) zum Bestimmen durch welchen von den parallelen Ästen das Gas strömt, aufweist, wobei die Regelmittel Mittel (14) umfassen, um die relative Feuchtigkeit von dem Gas, das den Behälter verlässt, zu bestimmen, und betriebsfähig sind, um einen Fluss durch den einen Ast (17) aufrechtzuerhalten, der einen offenen Durchgang aufweist, bis die relative Feuchtigkeit unter ein vorbestimmtes Niveau fällt, und um anschließend den Fluss durch den Ast zu beenden, und um einen Fluss in dem anderen Ast (18) zu initiieren und Mittel (16) umfasst, um eine Kondensation in dem Behälter zu messen, um einen Fluss in dem anderen Ast zu beenden, und um einen Fluss in dem einen Ast zu initiieren, wenn sich die erforderliche Kondensationsmenge in dem Behälter aufgebaut hat.

17. Vorrichtung nach Anspruch 16,
dadurch gekennzeichnet, dass
ein Gebläse (20) in der Leitung (12) zwischen dem Behälter (10) und den parallelen Ästen (17, 18) der Leitung zur Verfügung gestellt wird, um zu bewirken, dass ein Gas durch die Leitung strömt, und dass Ventilmittel (31) an dem Eingang zu dem ersten und zweiten Ast zur Verfügung gestellt sind, die selektiv betriebsfähig sind, um einen Fluss durch den einen oder den anderen der Äste zu ermöglichen.

18. Vorrichtung nach Anspruch 16,
dadurch gekennzeichnet, dass
Gebläse (19, 20) in beiden Ästen in der Leitung zur

Verfügung gestellt werden, die selektiv betriebsfähig sind, um einen Gasfluss durch den einen oder den anderen der Äste (17, 18) zu bewirken.

- 5 19. Vorrichtung nach einem der Ansprüche 16 - 18,
dadurch gekennzeichnet, dass
Mittel zur Verfügung gestellt werden, um das Gas/ die Dämpfe durch bzw. über den Behälter (10) zu verteilen, um sicherzustellen, dass an allen Oberflächen in dem Behälter Kondensat gebildet wird.
- 10 20. Vorrichtung nach einem der Ansprüche 16 - 19,
dadurch gekennzeichnet, dass
die Mittel zum Deaktivieren des Sterilisierungsmittels in dem einen Ast Mittel (22) aufweisen, um das Sterilisierungsmittel, das aus dem Behälter (10) extrahiert worden ist, in entsorgbare Bestandteile zu zerlegen.
- 15 21. Vorrichtung nach Anspruch 20,
dadurch gekennzeichnet, dass
das Sterilisierungsmittel Wasserstoffperoxiddampf und Wasserdampf ist, und die Mittel (22) zum Zerlegen des Sterilisierungsmittels katalytische Mittel aufweisen, die auf das Wasserstoffperoxid wirken, um das Wasserstoffperoxid in Wasserdampf und Sauerstoff zu zerlegen.
- 20 22. Vorrichtung nach einem der Ansprüche 16 - 21,
dadurch gekennzeichnet, dass
die Mittel (23) zum Erniedrigen der relativen Feuchtigkeit des umgewälzten Trägergases Kühlmittel aufweisen, um das Gas zu kühlen, um Feuchtigkeit daraus durch Kondensation zu extrahieren und Mittel (24) aufweisen, um das Gas im Anschluss an den Kondensationsprozess über Umgebungstemperatur zu erwärmen.
- 25 30 35 40

Revendications

1. Procédé de stérilisation d'une enceinte pouvant être fermée hermétiquement, comprenant les étapes qui consistent à faire circuler un gaz porteur et un agent stérilisant dans l'enceinte et dans un trajet d'écoulement ayant une sortie depuis l'enceinte et une entrée vers l'enceinte, tout agent stérilisant dans l'écoulement gazeux reçu de l'enceinte étant rendu apte à être rejeté, et la teneur en vapeur d'eau étant réduite, à la suite de quoi l'écoulement gazeux est chauffé et un agent stérilisant supplémentaire est ajouté pour stériliser l'enceinte, **caractérisé en ce que le trajet d'écoulement comporte deux branches parallèles, dans la première desquelles un agent stérilisant quelconque dans l'écoulement gazeux est rendu apte à être rejeté et toute vapeur d'eau contenue dans le gaz est réduite, et dans l'autre desquelles le gaz porteur est chauffé et de**
- 45 50 55

l'agent stérilisant est ajouté au gaz, le procédé comprenant en outre les étapes qui consistent à faire circuler initialement ledit gaz porteur dans ladite première branche, à contrôler la teneur en humidité du gaz dans l'enceinte et à arrêter l'écoulement de gaz porteur dans ladite première branche lorsque l'humidité relative dans l'enceinte a été réduite à un niveau prédéterminé tel que les surfaces de l'enceinte sont relativement sèches, à amorcer l'écoulement du gaz porteur dans ladite autre branche et à ajouter une vapeur ou des vapeurs stérilisantes au gaz passant dans l'autre branche jusqu'à ce qu'une condensation de l'agent stérilisant ait lieu dans l'enceinte, à arrêter l'apport d'agent stérilisant au gaz porteur, à continuer la circulation du gaz porteur sensiblement saturé en vapeur stérilisante pendant un temps prédéterminé pour assurer la stérilisation de l'enceinte, à arrêter l'écoulement dans ladite autre branche et à rediriger l'écoulement de gaz porteur dans ladite première branche afin d'extraire l'agent stérilisant de l'enceinte à gaz pour rendre l'agent stérilisant apte à être rejeté et pour réduire l'humidité relative du gaz porteur.

2. Procédé selon la revendication 1, dans lequel l'entrée vers une branche est fermée et l'entrée vers l'autre branche est ouverte et vice versa pour établir un écoulement dans l'une ou l'autre des branches.
3. Procédé selon la revendication 2, dans lequel des moyens à valves permettent un écoulement dans une branche et non dans l'autre branche, et vice versa.
4. Procédé selon la revendication 2, dans lequel des moyens à pompe sont utilisés dans le trajet d'écoulement pour faire circuler ledit gaz porteur.
5. Procédé selon la revendication 2, dans lequel des moyens à pompe sont prévus dans lesdites branches parallèles et sont utilisés pour provoquer un écoulement de gaz le long de l'une ou l'autre des branches parallèles dans le trajet d'écoulement.
6. Procédé selon l'une quelconque des revendications 1 à 5, dans lequel de la vapeur d'eau est extraite du gaz dans ladite première branche par refroidissement du gaz pour provoquer une condensation de la vapeur d'eau, le condensat résultant étant extrait.
7. Procédé selon la revendication 6, dans lequel le gaz refroidi dans ladite première branche est chauffé après ladite étape de refroidissement.
8. Procédé selon l'une quelconque des revendications précédentes, comprenant les étapes qui consistent à réduire initialement l'humidité relative dans l'enceinte à environ 30 à 40%, à faire circuler un gaz

porteur vers l'enceinte, à élever la température du gaz en circulation au-dessus de la température ambiante, à fournir une vapeur ou des vapeurs stérilisantes au gaz porteur en circulation, suffisantes pour saturer sensiblement le gaz grâce à quoi, lors d'un refroidissement dans l'enceinte, un condensat de la vapeur stérilisante se forme sur une surface dans l'enceinte, à distribuer le gaz/la vapeur dans toute l'enceinte pour assurer la formation du condensat sur toutes les surfaces dans l'enceinte, à mesurer la quantité de condensat formé sur une surface de l'enceinte et à continuer à faire circuler le gaz/la vapeur jusqu'à ce qu'une quantité demandée de condensat soit formée dans l'enceinte, à arrêter l'apport de vapeur stérilisante au gaz tout en continuant à faire circuler le gaz saturé/la vapeur afin de maintenir le condensat sur la surface pendant une période de temps prédéterminée, et à extraire finalement la vapeur stérilisante du gaz porteur tout en continuant à faire circuler le gaz porteur à travers l'enceinte afin d'extraire le condensat de l'enceinte.

9. Procédé selon la revendication 8, dans lequel la vapeur stérilisante est extraite du gaz porteur par dissociation de la vapeur en constituants pouvant être rejetés.
10. Procédé selon la revendication 8 ou 9, dans lequel la vapeur stérilisante est du peroxyde d'hydrogène et de la vapeur d'eau.
11. Procédé selon la revendication 10, dans lequel le peroxyde d'hydrogène extrait de la chambre avec le gaz en circulation est soumis à une action catalytique pour décomposer le peroxyde d'hydrogène en vapeur d'eau et en oxygène, la première étant extraite du gaz avant la recirculation du gaz à travers l'enceinte.
12. Procédé selon l'une quelconque des revendications 8 à 11, dans lequel l'étape initiale de réduction de l'humidité relative dans l'enceinte est exécutée en faisant circuler le gaz porteur à travers la chambre et en extrayant de la vapeur d'eau du gaz en circulation à l'extérieur de la chambre.
13. Procédé selon l'une quelconque des revendications 8 à 12, dans lequel l'humidité relative dans l'enceinte est réduite à environ 35%.
14. Procédé selon l'une quelconque des revendications 8 à 13, dans lequel l'enceinte est maintenue à ladite humidité relative réduite pendant une période de temps qui dépend de la taille de l'enceinte et au débit d'écoulement de gaz pour assurer la sécheresse desdites surfaces dans l'enceinte.

15. Procédé selon l'une quelconque des revendications 8 à 14, dans lequel le condensat est maintenu sur les surfaces à l'intérieur de l'enceinte pendant une période prédéterminée pour assurer la stérilisation des surfaces. 5
16. Appareil pour stériliser une enceinte (10) pouvant être fermée hermétiquement, comportant un circuit (12) pour l'écoulement d'un gaz ou de plusieurs gaz, le circuit ayant des moyens pour recevoir et raccorder une enceinte devant être stérilisée dans le circuit afin de former avec elle un circuit fermé, les moyens (19, 20) pour faire circuler un gaz dans le circuit et dans l'enceinte, et ayant deux branches parallèles (17, 18) dans le circuit dont une première contient des moyens (22) pour désactiver un agent stérilisant devant être ajouté au gaz porteur circulant dans le circuit et des moyens 23 destinés à déshumidifier le gaz, et l'autre de ces branches contient des moyens (25) destinés à chauffer le gaz et des moyens (26) destinés à fournir une vapeur ou des vapeurs stérilisantes au gaz, l'appareil comportant en outre des moyens de commande (13 à 16) destinés à déterminer dans quelle branche parallèle le gaz s'écoule, les moyens de commande comprenant des moyens (14) destinés à déterminer l'humidité relative du gaz sortant de l'enceinte et pouvant fonctionner de façon à maintenir un écoulement dans ladite première branche 17 dont le passage est ouvert jusqu'à ce que l'humidité relative tombe en dessous d'un niveau prédéterminé, puis à faire cesser l'écoulement dans cette branche et à amorcer l'écoulement dans l'autre branche (18), et des moyens (16) destinés à mesurer une condensation dans l'enceinte pour arrêter l'écoulement dans ladite autre branche et amorcer l'écoulement dans ladite première branche lorsque la quantité demandée de condensation s'est accumulée dans l'enceinte. 10 15 20 25 30 35 40
17. Appareil selon la revendication 16, **caractérisé en ce qu'un ventilateur (20) prévu dans le circuit (12) entre l'enceinte (10) et les branches parallèles (17, 18) du circuit pour provoquer un écoulement de gaz le long du circuit et des moyens à valves (31) sont prévus à l'entrée des première et seconde branches, lesquels peuvent être actionnés sélectivement pour permettre un écoulement dans l'une ou l'autre des branches.** 45 50
18. Appareil selon la revendication 16, **caractérisé en ce que des ventilateurs (19, 20) sont prévus dans les deux branches dans le circuit, lesquels peuvent être actionnés sélectivement pour provoquer un écoulement de gaz dans l'une ou l'autre des branches (17, 18).** 55
- 16 à 18, **caractérisé en ce que des moyens sont prévus pour distribuer le gaz/les vapeurs dans toute l'enceinte (10) afin d'assurer qu'un condensât est formé sur toutes les surfaces dans l'enceinte.**
20. Appareil selon l'une quelconque des revendications 16 à 19, dans lequel les moyens destinés à désactiver l'agent stérilisant dans ladite première branche comprennent des moyens (22) destinés à décomposer l'agent stérilisant extrait de l'enceinte (10) en constituants pouvant être rejetés.
21. Appareil selon la revendication 20, dans lequel l'agent stérilisant est de la vapeur de peroxyde d'hydrogène et de la vapeur d'eau et les moyens (22) destinés à décomposer l'agent stérilisant comprennent des moyens catalytiques destinés à agir sur le peroxyde d'hydrogène pour décomposer le peroxyde d'hydrogène en vapeur d'eau et en oxygène.
22. Appareil selon l'une quelconque des revendications 16 à 21, dans lequel les moyens (23) destinés à abaisser l'humidité relative du gaz porteur en circulation comprennent des moyens de réfrigération destinés à refroidir le gaz pour en extraire de l'humidité par condensation et des moyens (24) destinés à chauffer le gaz au-dessus de la température ambiante à la suite dudit processus de condensation.

FIG. 1

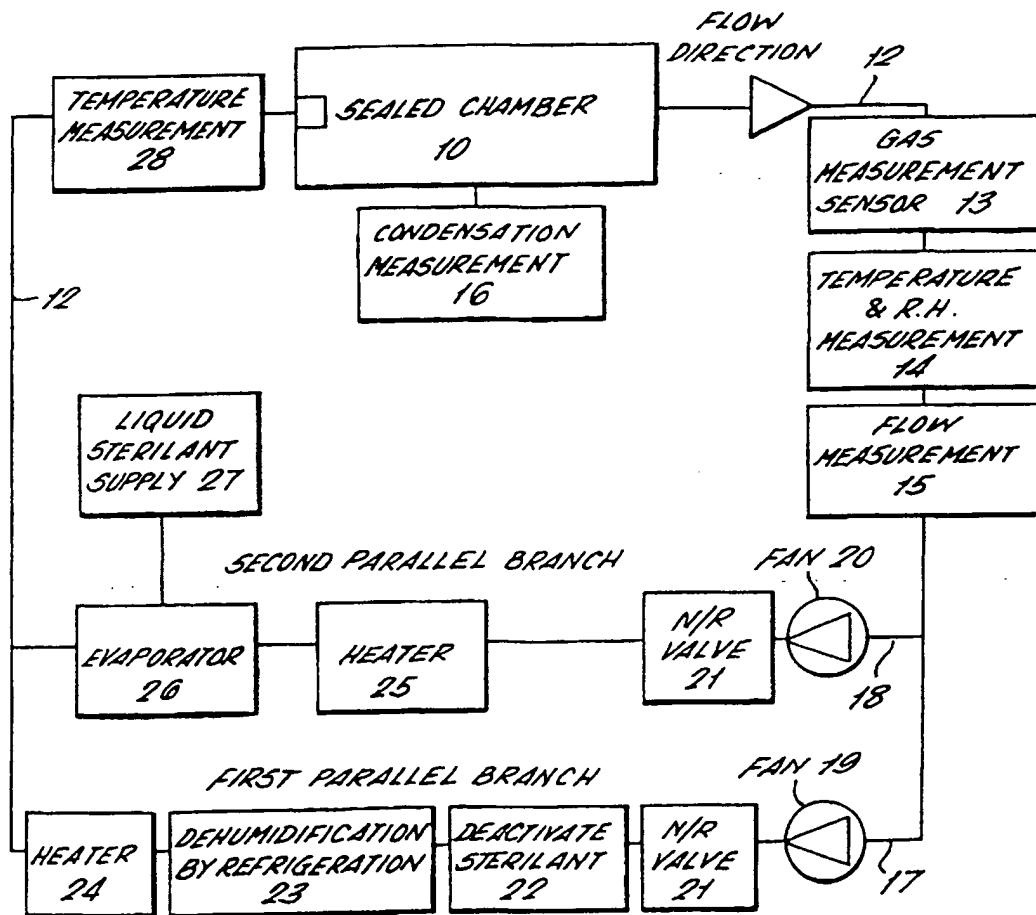


FIG. 2

